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10/567,558

04/06/2007

Jurgen Jaeger

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EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/567,558 | <b>Applicant(s)</b><br>JAEGER ET AL. |  |
|                              | <b>Examiner</b><br>Deepak Rao        | <b>Art Unit</b><br>1624              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>20060208, 20071218 &amp; 20081006</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 1-5 are pending in this application.

#### ***Claim Objections***

Claims 1-5 are objected to because of the following informalities:

The instant claims 1, 3, 4 and 5 do not appear to end with a 'period' ( . ).

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to 'a process to prepare a compound of formula 5' and the claim recites steps a), b) or c) to prepare the compound. The claim, however, recites that 'if desired, the compound of formula 5 is transformed into the compound of formula I'. This is not understood as the claim is drawn to the preparation of compound of formula 5, why it would be desired to prepare any other compound from that.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Masciadri, U.S. Patent No. 5,773,446. The instant claims read on reference disclosed process of preparation of compound of formula I. See the reference disclosed compounds of formula I in col. 1 and the corresponding compound 5-(2-cyclopropyl-7,8-dimethoxy-2H-1-benzopyran-5-yl-methyl)-pyrimidine-2,4-diamine (Example 4). The reference teaches a process of preparation of the reference compounds - starting from compound of formula (13) by first reducing the compound, followed by oxidizing to prepare the aldehyde of formula (4), which is then transformed into the compound of formula III, wherein X is an arylamino such as anilino, which compound of formula III is reacted with guanidine to provide the product of formula I. The reference disclosed process is identical to that of steps b) and d) of claims 1 and 3.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masciadri, U.S. Patent No. 5,773,446, in view of EP 629619.

The primary reference, Masciadri (US'446) teaches a process to prepare a compound of formula I, starting from a compound of formula (13), via the steps of forming compounds of formula (4) and III, see the reaction scheme in col. 5-6 and the explanation of the process in col. 1-6 and the examples.

The instant claims differ by reciting steps a) or c) which involve cyclization step using an acetal of formula 9.

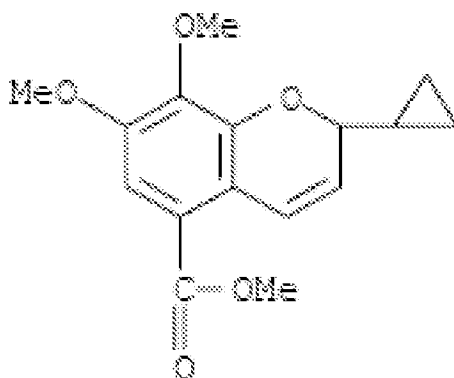
The secondary reference, EP'619 in the analogous art of preparing pyranyl compound teaches the condensation of phenol of formula II with an acetal of formula III to prepare the corresponding pyranyl compound, see the reference disclosure in pages 3 and 5.

Therefore, one of ordinary skill in the art would have been motivated to modify the process of the primary reference by reacting the phenol of formula (1) of the primary reference with an acetal to provide the corresponding pyranyl compound (4), e.g., 2-cyclopropyl-7,8-dimethoxy-2H-1-benzopyran-5-carbaldehyde (the compound of Example 3). Such modification would have been obvious to one having ordinary skill because the skilled artisan would have the reasonable expectation of obtaining products consistent with reference teachings.

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2. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masciadri, U.S. Patent No. 5,773,446. The reference teaches methyl ester of a pyranyl compound of formula (13), see for example, the product of Example 3, step a) in col. 10 (compound depicted below for convenience):

<sup>1</sup> Methyl (RS)-2-cyclopropyl-7,8-dimethoxy-2H-1-benzopyran-5-carboxylate was obtained as white crystals.



The compound is taught to be useful as an intermediate in the preparation of other compounds having antibiotic properties, see for example, col. 1-6. The instant claim is drawn to a pyranyl compound wherein the 5-position has a carboxylic acid group (i.e., -COOH group) as compared to the methyl ester group (i.e., -COOMe) for the reference compound. Therefore, the instantly claimed compounds differ from the reference compounds by having H in place of methyl group (i.e., H vs. Methyl). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the reference compounds to prepare the structural analog. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such structurally analogous compounds are expected to possess similar properties and therefore, the same use as taught for the reference compounds, i.e., useful as intermediates in the preparation of other useful products.

***Allowable Subject Matter***

Claim 5 is allowable if rewritten to overcome the objection of the instant office action. The references of record do not teach or fairly suggest the compound of formula 4 of instant claim.

Receipt is acknowledged of the Information Disclosure Statements filed on February 8, 2006; December 18, 2007 and October 6, 2008 and a copy is enclosed herewith.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Deepak Rao/  
Primary Examiner  
Art Unit 1624**

April 1, 2010